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**REMARKS**

Claims 1-4, 8-51, and 55-58 are currently pending in this application. Previously pending claims 5, 7, and 52-54 are canceled. Claims 1-4, 8-51, and 55-58 are finally rejected.

Applicants gratefully acknowledge the Examiner's favorable reconsideration and withdrawal of the previous 35 U.S.C. §112 new matter rejection of claims 55-57.

Claim 1 is amended to specifically recite particular novel and beneficial features of the composition, and to delete reference to a self-emulsifying drug delivery system. Support for this amendment can be found on page 3, lines 4-8 and page 15, lines 4-8.

Claim 2 is amended to specifically recite particular novel and beneficial features of the composition. Support for this amendment can be found on page 15, lines 4-8 and 12-13.

Claims 8-10, 17-19, 23-25, 27-30, 36-38, 40-42, 47-48, and 51 are amended to correct claim language informalities and to better present the invention.

No new matter has been added by way of these amendments.

**I. Rejection under 35 U.S.C. §112 – New Matter**

Claims 1-5 and 7 – 58 are rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. The Examiner alleges that the recitation of a self emulsifying system is new matter.

The amended claims no longer make reference to a self emulsifying system. In view of these amendments, Applicants respectfully request that this rejection be withdrawn.

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**II. Rejections under 35 U.S.C. §102**

***Grebow:***

Claims 1-4, 32, 33, 36, 37, 39, 41-44, 47, 48, 51, 52, 54, and 58 are rejected under 35 U.S.C. §102(b) as being anticipated by Grebow, et al. (US 5,618,845). The Examiner alleges that Grebow discloses modafinil particles in suspension or emulsion.

Grebow mentions suspensions or emulsions in only two places. First, at column 8, lines 22-26, Grebow discloses a simple two component suspension of solid, presumably crystalline particles of modafinil in water. The suspension contains no surfactant. Second, at column 10, lines 18-21, Grebow states generally that a pharmaceutical composition comprising modafinil particles can be administered "orally in the form of a vehicle such as a tablet, capsule, powder, pill, liquid/*suspension* or *emulsion*." (emphasis added) Again, there is no disclosure of a surfactant.

Grebow fails to disclose, either explicitly or inherently, a non-aqueous particle-forming composition comprising a modafinil compound and a surfactant, let alone a composition that spontaneously forms a homogeneous, stable composition of non-crystalline particles when contacted with an aqueous medium. Accordingly, Grebow fails to disclose each limitation of independent claim 1 or any claim dependent thereon.

In view of the fact that Grebow fails to disclose the compositions of the present invention, Grebow is not an anticipatory reference. Applicants respectfully request that this rejection be withdrawn.

***Nguyen:***

Claims 1-4, 7, 11, 14, 15, 32, 33, 36, 37, 39, 47, 51 and 54 are rejected under 35 U.S.C. §102(b) as being anticipated by Nguyen et al. (US 5,843,347). The Examiner alleges that

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Nguyen discloses modafinil particles in suspension or emulsion or oil-water emulsion at column 5, lines 55-65 and column 7, lines 27-30.

At both column 5, lines 55-65 and column 7, lines 27-30, Nguyen discloses an oil-in-water suspension/emulsion containing water, an active ingredient, a high molecular weight polymer, a water-soluble or water-dispersible component, and a lipophilic excipient, which is not defined. The suspension/emulsion is prepared by mixing the individual components and then stirring at high rpm to achieve homogeneity (*see* col. 11, lines 25-30). There is no disclosure of a non-aqueous particle-forming composition, and no disclosure of spontaneous formation of an aqueous, homogeneous, stable composition.

Nguyen fails to disclose, either explicitly or inherently, a non-aqueous particle-forming composition comprising a modafinil compound and a surfactant, let alone an aqueous, homogeneous, stable composition containing non-crystalline particles comprising the modafinil compound spontaneously formed from such a composition. Accordingly, Nguyen fails to disclose each limitation of independent claim 1 or any claim dependent thereon.

In view of the fact that Nguyen fails to disclose the compositions of the present invention, Nguyen is not an anticipatory reference. Applicants respectfully request that this rejection be withdrawn.

### III. Rejections under 35 U.S.C. §103

#### *Grebow:*

Claims 17, 18, 34, 35, 38, 45, 46, 49, 50 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grebow et al. (US 5,618,845). The Examiner alleges that the formulation of Grebow forms an emulsion.

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As discussed above, Grebow mentions suspensions or emulsions in only two places. At column 8, lines 22-26, Grebow discloses a suspension containing only water and modafinil. There is no teaching or suggestion of a surfactant. At column 10, lines 18-21, Grebow states that modafinil particles can be administered in a liquid/suspension or emulsion. There is no teaching or suggestion of a surfactant. Accordingly, Grebow fails to teach or suggest each limitation of independent claim 1 or any claim dependent thereon.

In view of the fact that Grebow fails to teach or suggest the compositions of the present invention, Grebow cannot render obvious the rejected claims. Applicants respectfully request that this rejection be withdrawn.

***Nguyen in view of Lafon:***

Claims 8-10, 13, 17-20, 34, 35, 38 and 40-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen et al. (US 5,843,347) in view of Lafon (US 5,180,745). The Examiner alleges that Nguyen discloses isotropic, non-crystalline modafinil, and suspensions/emulsions.

As discussed above, at both column 5, lines 55-65 and column 7, lines 27-30 Nguyen discloses an oil-in-water suspension/emulsion containing water, an active ingredient, a high molecular weight polymer, a water-soluble or water-dispersible component, and a lipophilic excipient. There is no teaching or suggestion of a non-aqueous particle-forming composition comprising a modafinil compound and a surfactant. There is no teaching or suggestion of spontaneous formation of an aqueous, homogeneous, stable composition containing non-crystalline particles comprising the modafinil compound. Accordingly, Nguyen fails to teach or suggest each limitation of independent claim 1 or any claim dependent thereon.

Lafon fails to cure the deficiencies of Nguyen. According to the Examiner, Lafon is relied upon for a teaching/disclosure that modafinil is used to treat Parkinson disease and not on

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the form of the modafinil formulation.

In view of the fact that Nguyen, alone or in combination with Lafon, fails to teach or suggest the compositions of the present invention, Nguyen and Lafon cannot render obvious the rejected claims. Applicants respectfully request that this rejection be withdrawn.

***Grebow in view of Lafon:***

Claims 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grebow et al. (US 5,618,845) in view of Lafon (US 4,927,855). The Examiner alleges that the formulation of Grebow is an emulsion.

As discussed above, Grebow fails to teach or suggest each limitation of independent claim 1 or any claim dependent thereon.

Lafon fails to cure the deficiencies of Grebow, because Lafon is not relied on for a teaching of the form of the modafinil formulation.

In view of the fact that Grebow, alone or in combination with Lafon, fails to teach or suggest the compositions of the present invention, Grebow and Lafon cannot render obvious the rejected claims. Applicants respectfully request that this rejection be withdrawn.

**IV. Double Patenting Rejection**

Claims 1, 3-5, 14, 15, 32-35 and 44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7, 8, 10-13, 26-29, 31 and 32 of US Patent No. 6,489,363.

Without agreeing to the substantive basis of the Examiner's rejection, and in order to expedite the prosecution, applicants will submit a Terminal Disclaimer in compliance with 37 CFR § 1.321(c) upon recognition of the allowability of any pending claims. Applicants

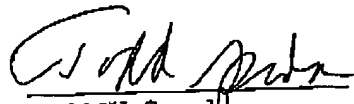
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respectfully point out that the present application and the '363 patent are commonly owned.

**Conclusion**

For at least the reasons set forth herein, Applicants respectfully submit that each rejection and objection has been addressed. It is believed that all the claims are in form for allowance, and an early notification to that end is respectfully requested. Applicants invite the Examiner to contact the undersigned at (610) 883-5679 to clarify any remaining issues.

Respectfully submitted,

  
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